K001993

NOV 1 3 2000

Summary of Safety and Effectiveness

Submitted by:

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Device Name:

Sof-Tact™ Diabetes Management System
SoftSense™ Diabetes Management System

Common Name:

Self-Monitoring Blood Glucose System

Classification:

Glucose Test System
Class II per 21 CFR 862.1345

Predicate Devices:

Precision Xtra™Advanced Diabetes Management System—K983504
Amira AtLast Blood Glucose Monitoring System--K982076
TheraSense FreeStyle™ Blood Glucose Monitoring System--K992684

Description:

The MediSense Sof-Tact™ Diabetes Management System for Blood Glucose Testing utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions. The Sof-Tact Diabetes Management System integrates the process of blood collection from body sites including the forearm, upper arm and base of the thumb and glucose assay into a single operation by the user. A separate test port is available for blood collection glucose assay from the fingertip.

Intended Use:

The Sof-Tact Diabetes Management System is intended for in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Sof-Tact is for home (lay user). The Sof-Tact Diabetes Management System is specifically intended for the quantitative measurement of glucose in whole blood samples obtained from the finger, forearm, upper arm and base of the thumb.

Comparison to Predicate Device: The Sof-Tact Diabetes Management System has equivalent technological characteristics and a similar intended used as the Precision Xtra System (K983504), TheraSense FreeStyle Meter (K992684) and the Amira AtLast Meter (K982076).

Performance Studies: The performance of the Sof-Tact Diabetes Management System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose that are substantially equivalent to the current methods for blood glucose measurements, which include the predicate devices listed above.

Conclusion: Results of laboratory and clinical testing demonstrate that the performance of the Sof-Tact Diabetes Management System, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate devices for blood glucose testing. In addition, results of clinical performance testing demonstrate that trained operators and lay users obtain equivalent whole blood glucose results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2000

Joseph O. Magliozzi, RAC
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Bedford, Massachusetts 01730-1402

Re: K001993
Trade name: Sof-Tact™ Diabetes Management System
Regulatory Class: II
Product Code: NBW, LFR
Dated: September 26, 2000
Received: September 27, 2000

Dear Mr. Magliozzi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K001993

Device Name: Sof-Tact™ Diabetes Management System

Indications For Use:

The Sof-Tact Diabetes Management System is intended for in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Sof-Tact System is for home (lay user) use.

The Sof-Tact Diabetes Management System is specifically intended for the quantitative measurement of glucose in whole blood samples obtained from the finger, forearm, upper arm and the base of the thumb.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001993

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use X
(Per 21 CFR 801.108)